Duke | MARGOLIS INSTITUTE for Health Policy

Enhancing Adoption of Innovative Clinical Trial Approaches

Hybrid Public Meeting • Kellogg Conference Hotel • Washington, D.C.

March 19, 2024 | 10:00 am – 5:00 pm ET

March 20, 2024 | 12:30 pm – 5:00 pm ET

Agenda: Day 1

10:00 am **Welcome**

Mark McClellan, Duke-Margolis Institute for Health Policy

10:10 am **Fireside Chat**

Mark McClellan, Duke-Margolis Institute for Health Policy
Patrizia Cavazzoni, U.S. Food and Drug Administration

U.S. Food and Drug Administration leadership will introduce the meeting's objectives, while highlighting ongoing activities and initiatives in the clinical trial innovation space within the Center for Drug Evaluation and Research (CDER).

10:30 am **Session 1: Evolution of Clinical Trial Research and the Current State of Trial Innovation**

Moderator: Mark McClellan, Duke-Margolis Institute for Health Policy

Panelists will discuss current healthcare trends and how the landscape of clinical trial innovations have been evolving to meet the pressing health care challenges of tomorrow.

Panelists:

- Monica Bertagnolli, National Institutes of Health
- Ned Braunstein, Regeneron
- Patrizia Cavazzoni, U.S. Food and Drug Administration
- Esther Krofah, Milken Institute
- Robert Metcalf, Eli Lilly
- Janet Woodcock, U.S. Food and Drug Administration (Retired)

11:30 am **Break**

11:40 am **Session 2: Regulatory and Compliance Considerations**

Moderator: Morgan Hanger, Clinical Trials Transformation Initiative

Panelists will examine implementation of innovative clinical trials from a regulatory standpoint. Discussion will cover the exploration of practical opportunities to adopt innovative approaches from compliance of Good Clinical Practice and other guidelines.

Panelists:

- M. Khair ElZarrad, U.S. Food and Drug Administration
- Nancy Kass, Johns Hopkins University
- Martin Landray, Protas and Good Clinical Trials Collaborative
- Bea Lavery, Genentech
- Nicole Mayer Hamblett, Seattle Children's Research Institute (Cystic Fibrosis Foundation)
- Amy McKee, Parexel

12:55 pm **Lunch Break**

02:10 pm **Session 3: Patient-Centric and Recruitment Considerations**

Moderator: Jennifer Urwongse, PPD

Panelists will highlight factors related to patient-centric design and execution in innovative clinical trials. Discussion will encompass opportunities to incorporate patient perspectives in trial design, facilitate recruitment and retention, ensure informed consent, and optimize other processes for enhancing clinical trial participation.

Panelists:

- Jacqueline Corrigan-Curay, U.S. Food and Drug Administration
- David Feldman, National Kidney Foundation
- Marilyn Metcalf, GSK
- Al Richmond, Community-Campus Partnerships for Health
- Pamela Tenaerts, Medable

03:25 pm **Break**

03:35 pm **Session 4: Infrastructure and Organizational Considerations**

Moderator: Donna Cryer, Global Liver Institute

Panelists will evaluate innovative approaches to clinical trials within existing infrastructure and health care delivery systems. Discussion will focus on opportunities to bolster technical and analytical capabilities, organizational culture for participation in research, site readiness to conduct research, and access to research.

Panelists:

- David Burrow, U.S. Food and Drug Administration
- Rob DiCicco, TransCelerate BioPharma
- Laura Esserman, University of California San Francisco
- John Halamka, Mayo Clinic
- Anastasia Lesogor, Novartis
- Cynthia Verst, IQVIA

04:50 pm **Closing Remarks**

Gerrit Hamre, Duke-Margolis Institute for Health Policy

05:00 pm **Adjournment**

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Agenda: Day 2

12:30 pm **Welcome and Day 1 Recap**

Mark McClellan, Duke-Margolis Institute for Health Policy

12:45 pm **Session 5: Global Regulatory Collaboration on Clinical Trial Innovation**

Moderator: Peter Stein, U.S. Food and Drug Administration

Regulatory agencies representing several jurisdictions will share internal collaborations, future outlook, and anticipated goals to further cultivate clinical trial innovation globally. Organizations representing prospective clinical trial sponsors will also share their perspectives on opportunities to enhance harmonization worldwide.

Panelists:

- Yuki Ando, Pharmaceuticals and Medical Devices Agency
- Lucia D'Apote, Amgen (European Federation of Pharmaceutical Industries and Associations)
- M. Khair ElZarrad, U.S. Food and Drug Administration
- Sarem Sarem, Health Canada
- Andrew Thomson, European Medicines Agency
- John Zhong, REGENXBIO (Pharmaceutical Research and Manufacturers of America)

01:55 pm **Break**

02:05 pm **Session 6: Collaborations Across Industries to Leverage Innovation**

Moderator: Ryan Ferguson, U.S. Department of Veteran Affairs

Clinical research stakeholders will share their experiences and insights from collaborating to implement innovative clinical trials and explore adoption strategies across the clinical research ecosystem. Panelists will explore enacted innovative approaches to clinical trials including use of novel tools for trial design and use of real-world data and real-world evidence. Point-of-care, platform, decentralized and pragmatic trial designs will also be discussed.

Panelists:

- Stacey Adam, Foundation for the National Institutes of Health
- Jeff Allen, Friends of Cancer Research
- John Concato, U.S. Food and Drug Administration
- Angie Goldsberry, Biogen
- Luke Kosinski, Critical Path Institute
- Neal Meropol, Flatiron Health

03:20 pm **Break**

03:30 pm **Session 7: Future Directions on Clinical Trial Innovation**

Moderator: Kevin Bugin, U.S. Food and Drug Administration

Panelists will summarize key insights and takeaways from the workshop discussions and reflect on potential next steps for CDER and its partners to consider in support of innovative clinical trials. Discussion will also think through continued engagement and connection with CDER's innovation efforts by industry, academic, patient, and other stakeholders. Panelists will highlight the impact of clinical trial innovation and how success for implementation can be measured.

Panelists:

- Amy Abernathy, Verily
- Amy Bertha, Bayer (Biotechnology Industry Organization)
- Micky Cohen-Wolkowiez, Duke Clinical Research Institute
- Craig Lipset, Decentralized Trials and Research Alliance
- Martin Mendoza, National Institutes of Health
- Richard Schilsky, Reagan-Udall Foundation for the FDA

04:45 pm **Closing Remarks**

Gerrit Hamre, Duke-Margolis Institute for Health Policy

05:00 pm **Adjournment**

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